

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

NOTICE OF PROPOSED RULEMAKING

TITLE 22, CALIFORNIA CODE OF REGULATIONS

**AMENDMENT TO SECTION 12705
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK**

**AMENDMENT TO SECTION 12805
SPECIFIC REGULATORY LEVELS: CHEMICALS CAUSING REPRODUCTIVE
TOXICITY**

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment proposes to establish specific regulatory levels posing no significant risk for 1,2-dichloropropane and naphthalene, amend Title 22, California Code of Regulations, Section 12705(b), to establish specific regulatory levels representing 1/1000th the no observable effect level for 1,2-dibromo-3-chloropropane, disodium cyanodithioimidocarbonate, ethyl dipropylthiocarbamate, ethylene glycol monomethyl ether, ethylene glycol monomethyl ether acetate, methyl bromide as a structural fumigant, sodium dimethyldithiocarbamate and thiophanate-methyl and amend Title 22, California Code of Regulations, Section 12805.

PUBLIC PROCEEDINGS

A public hearing will be held on **August 23, 2004**, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. The public hearing will commence at 10:00 a.m. in the Coastal Hearing Room, California Environmental Protection Agency Building, 1001 I Street, 2nd Floor, Sacramento, California and will last until all business has been conducted, or until 5:00 p.m.

Any written statements or arguments regardless of the form or method of transmission must be received by OEHHA by 5:00 p.m. on **August 23, 2004**, which is hereby designated as the close of the written comment period.

Written comments regarding this proposed action can be sent by mail or by fax addressed to:

Susan Luong
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation Program
P. O. Box 4010
Sacramento, California 95812-4010
FAX: (916) 323-8803
Telephone: (916) 445-6900

Comments sent by courier should be delivered to:

Susan Luong
Office of Environmental Health Hazard Assessment
1001 I Street, 19th Floor
Sacramento, California 95814

Comments may also be transmitted via email addressed to: (sluong@oehha.ca.gov).

It is requested but not required that written statements or arguments be submitted in triplicate.

If you have special accommodation or language needs, please contact Susan Luong at (916) 445-6900 or sluong@oehha.ca.gov by August 9, 2004. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT

Please direct inquiries concerning the substance and processing of the action described in this notice to Susan Luong, in writing at the address given above, or by telephone at (916) 445-6900. Ms. Cynthia Oshita is a back-up contact person for inquiries concerning processing of this action and is available at the same telephone number.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq. and commonly known as Proposition 65 (hereinafter referred to as “Proposition 65” or “the Act”), prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code section 25249.6). The Act also prohibits such persons from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water (Health and Safety Code section 25249.5).

For chemicals known to the State to cause cancer, an exemption from the above requirements is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible poses no significant risk or that a discharge which otherwise complies with all applicable requirements would not cause any significant amount of the discharged or released chemical to enter any source of drinking water (Health and Safety Code sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk may be made utilizing regulations that have previously been adopted by the Office of Environmental Health Hazard Assessment (Title 22, California Code of Regulations, Sections 12701-12721¹). Section 12701 describes alternative methods for making such a determination. Section 12705 sets forth the process by which the Office of Environmental

¹ All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

Health Hazard Assessment may identify specific regulatory levels for determining “no significant risk” for purposes of Proposition 65.

For chemicals known to the State to cause reproductive toxicity, an exemption from the warning requirement is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible produces no observable reproductive effect, assuming exposure at 1,000 times the level in question (Health and Safety Code sections 25249.10 and 25249.11). The maximum dose level at which a chemical has no observable reproductive effect is referred to as the no observable effect level (NOEL). The Act also provides an exemption from the prohibition against discharging a listed chemical into sources of drinking water if the amount discharged does not constitute a “significant amount,” as defined, and the discharge is in conformity with all other laws and regulatory requirements (Health and Safety Code sections 25249.9 and 25249.11). The term “significant amount” is defined in a manner that equates to the level that triggers the warning requirement. Thus, these exemptions apply when an exposure or discharge does not exceed the NOEL divided by 1,000. One method by which a person in the course of doing business may determine whether an exposure or a discharge is exempt from the Act is by application of the specific regulatory level for the chemical in Section 12805. The levels in Section 12805 represent the maximum dose level at which the chemical has no observable reproductive effect, given an exposure at one thousand (1,000) times the level in question.

Regulations previously adopted by the Office of Environmental Health Hazard Assessment (OEHHA) provide guidance for determining whether an exposure to, or a discharge of, a chemical known to cause reproductive toxicity meets the statutory exemption (Sections 12801-12821). These regulations provide three ways by which a person in the course of doing business may make such a determination: (1) by conducting a risk assessment in accordance with the principles described in Section 12803 to derive a NOEL, and dividing the NOEL by 1,000; or (2) by application of the specific regulatory level adopted for the chemical in Section 12805; or (3) in the absence of such a level, by using a risk assessment conducted by a state or federal agency, provided that such assessment substantially complies with Section 12803(a). The specific regulatory levels in Section 12805 represent one one-thousandth of the NOEL.

This proposed regulation sets forth no significant risk levels (NSRLs) for adoption into Section 12705(b) using scientific methods consistent with procedures outlined in Section 12703. This proposed regulation also sets forth maximum allowable dose levels (MADLs) for adoption into Section 12805 using scientific methods outlined in Section 12803.

Details on the scientific basis for the proposed numbers are provided in the references cited below, which are also included in the rulemaking record. The references are risk assessment documents prepared by OEHHA describing and summarizing the derivation of the regulatory levels listed below.

The proposed levels described below for inclusion in Section 12705 represent the levels of exposure to the chemical which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the following risk assessment document(s) prepared by the

OEHHA, Reproductive and Cancer Hazard Assessment Section, in accordance with the principles in Section 12703.

This amendment to Section 12705(b) would adopt the following “no significant risk” levels for chemicals listed under Proposition 65 as known to cause cancer:

| Chemical | NSRL, in units micrograms per day | Reference |
|---------------------|--------------------------------------|---------------|
| 1,2-Dichloropropane | 9.7 | OEHHA (2004a) |
| Naphthalene | 5.8 | OEHHA (2004b) |

Levels established for carcinogens in Section 12705(b) supersede any existing levels for these carcinogens in Section 12705(c) and Section 12705(d).

This amendment to Section 12805 would adopt the following regulatory level for chemicals listed under Proposition 65 as known to cause reproductive toxicity:

| Chemical | MADL, in units micrograms per day | Reference |
|--|---|---------------|
| 1,2-Dibromo-3-chloropropane | 4.3 (inhalation) 3.1 (oral) | OEHHA (2004c) |
| Disodium cyanodithioimidocarbonate | 56 (oral) 170 (oral; as 32% pesticidal formulation) | OEHHA (2004d) |
| Ethyl dipropylthiocarbamate | 700 (oral and inhalation) 6700 (dermal) | OEHHA (2004e) |
| Ethylene glycol monomethyl ether | 63 (oral) | OEHHA (2004f) |
| Ethylene glycol monomethyl ether acetate | 98 (oral) | OEHHA (2004g) |
| Methyl bromide as a structural fumigant | 810 (inhalation) | OEHHA (2004h) |
| Sodium dimethyldithiocarbamate | 23 (oral) 58 (oral; as 40% pesticidal formulation) | OEHHA (2004i) |
| Thiophanate-methyl | 600 (oral) | OEHHA (2004j) |

The risk assessments which were used by OEHHA to determine the proposed levels are as follows:

Office of Environmental Health Hazard Assessment (OEHHA, 2004a). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen 1,2-Dichloropropane. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004b). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Naphthalene. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004c). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for 1,2-Dibromo-3-chloropropane (DBCP). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004d). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Disodium Cyanodithioimidocarbamate (DCDIC) for Oral Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004e). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Ethyl Dipropylthiocarbamate (EPTC). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004f). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Ethyl Glycol Monomethyl Ether. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004g). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Ethyl Glycol Monomethyl Ether Acetate. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004h). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Methyl Bromide as A Structural Fumigant. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004i). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Sodium Dimethyldithiocarbamate for Oral Exposures. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, June, 2004.

Office of Environmental Health Hazard Assessment (OEHHA, 2004j). Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Thiophanate-methyl for the Oral Route of Exposure. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May, 2004.

AUTHORITY

Health and Safety Code section 25249.12.

REFERENCE

Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

OEHHA has determined the proposed regulatory action would not pose a mandate on local agencies or school districts; nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

COSTS OR SAVINGS TO STATE AGENCIES

OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

EFFECT ON HOUSING COSTS

OEHHA has determined that the proposed regulatory action will have no effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

OEHHA has made an initial determination that the adoption of the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. OEHHA believes the proposed amendments to the regulation could provide clarity and certainty for businesses that must comply with Proposition 65.

IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS/BUSINESSES

OEHHA has determined that the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

OEHHA is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

EFFECT ON SMALL BUSINESSES

OEHHA has determined that the proposed regulation will not impose any requirements on small business. Rather, the proposed regulation will assist small businesses subject to the Act in determining whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), OEHHA must determine that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

OEHHA has prepared and has available for public review an Initial Statement of Reasons for the regulation, all the critical information upon which the regulation is based, and the text of the regulation. A copy of the Initial Statement of Reasons, a copy of the text of the regulation and copies of the risk assessments which were used by OEHHA to determine the NSRLs and MADLs are available upon request from OEHHA's Proposition 65 Implementation Program at the address and telephone number indicated above. These documents are also posted on OEHHA's Web site at www.oehha.ca.gov.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on changed regulations and the full text will be mailed to individuals who testified or submitted oral or written comments at the public hearing, whose comments were received by OEHHA during the public comment period, and who request notification from OEHHA of availability of such change. Copies of the notice and the changed regulation will also be available at the OEHHA's Web site at www.oehha.ca.gov.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons may be obtained, when it becomes available, from OEHHA's Proposition 65 Implementation Program at the address and telephone number

indicated above. The Final Statement of Reasons will also be available at the OEHHA's Web site at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Deputy Director, External and Legislative Affairs

Dated: July 2, 2004